

WET N WILD FERGIE BB CREAM SPF 15- titanium dioxide cream
Markwins Beauty Products Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient

Titanium Dioxide 3.8%

Use

Helps prevent sunburn

Directions

Apply liberally 15 minutes before sun exposure

Reapply at least every 2 hours

Use a water resistant sunscreen if swimming or sweating

Children under 6 months: Ask a doctor

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

For external use only

Do not use on damaged or broken skin.

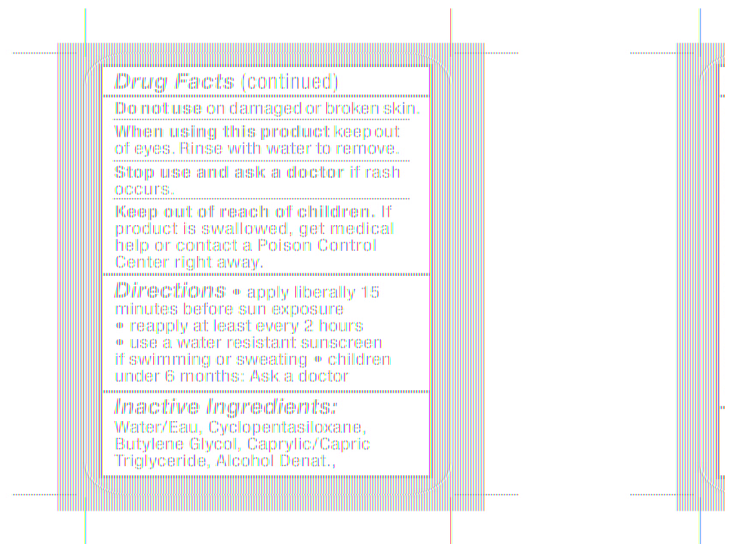
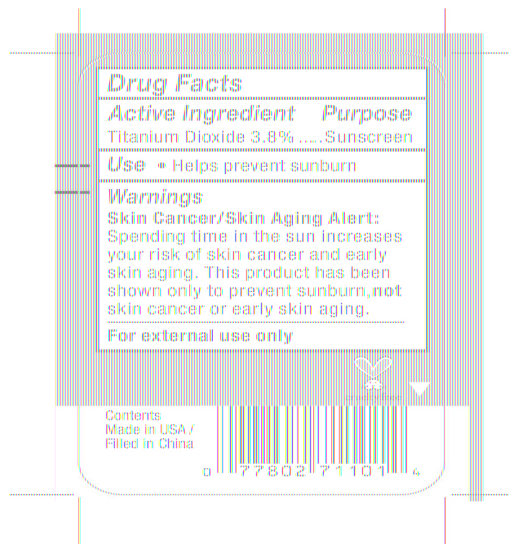
When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Inactive Ingredients

Water/Eau, Cyclopentasiloxane, Butylene Glycol, Caprylic/Capric Triglyceride, Triethylhexanoin, Cyclohexasiloxane, Alcohol Denat., Cetyl PEG/PPG-10/1 Dimethicone, Squalane, Polyglyceryl-4 Isostearate, Disteardimonium Hectorite, PEG-32, Aloe Barbadensis Leaf Juice, Alumina, Calcium Aluminum Borosilicate, Caprylyl Glycol, Cucumis Sativus (Cucumber) Fruit Extract, Dimethicone, Dimethicone/Vinyl Dimethicone Crosspolymer, Disodium EDTA, Ethylhexylglycerin, Glycerin, Hexylene Glycol, Panthenol, Retinyl Palmitate, Stearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Sodium Dehydroacetate, Phenoxyethanol, [+/- (MAY CONTAIN/PEUT CONTENIR): Mica, Titanium Dioxide/CI 77891, Iron Oxides/CI 77491, CI 77492, CI 77499]



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WET N WILD FERGIE BB CREAM SPF 15

titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:12027-105

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	3.8 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
CYCLOMETHICONE 5 (UNII: 0THF5PC10R)	
1,3-BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
TRIETHYLHEXANO IN (UNII: 7K3W1BIU6K)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	
ALCOHOL (UNII: 3K9958V90M)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)	
SQUALANE (UNII: GW89575KF9)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
POLYETHYLENE GLYCOL 1450 (UNII: OJ4Z5Z32L4)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM OXIDE (UNII: LM26O6933)	
CALCIUM ALUMINUM BORO SILICATE (UNII: 3JRB8A35M0)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CUCUMBER (UNII: YY7C30VXJT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
PANTHENOL (UNII: WV9CM0O67Z)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MICA (UNII: V8A1AW0880)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12027-105-11	30 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/31/2013	

Labeler - Markwins Beauty Products Inc. (135407760)

Registrant - Markwins Beauty Products Inc. (135407760)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Formula Inc		825048945	manufacture(12027-105)

Revised: 5/2013

Markwins Beauty Products Inc.